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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,575	01/09/2001	Joerg Kaufmann	PP-01656.002/200130.517	9437

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EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 11/18/2004 13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/758,575	KAUFMANN ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *November 14, 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *12-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *04/16/01; 08/07/01*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I (claims 1-11) in the reply filed on November 14, 2002 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 1-35 are pending.

Claims 12-35, drawn to non-elected inventions are withdrawn from examination.

Claims 1-11 are examined on the merits.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-11 are broadly drawn to an isolated nucleic acid molecule comprising a polynucleotide which is the polynucleotide complement of the polynucleotide of sections

a, b and c of claim 1, and at least 90% identical to the polynucleotide sequence of sections a, b, c and d of claim 1, wherein the polynucleotide encodes for SEQ ID NO: 2. In addition, the claims also are broadly drawn to the said nucleic acids and their complements thereof packaged in a recombinant vector and contained in host cells and the method for producing the encoded polypeptides. The specification while being enabling for the nucleic acid identified as SEQ ID NO: 1 which encodes the amino acid sequence, SEQ ID NO: 2, does not reasonably provide enablement for variants that have at least 90% sequence identity to polynucleotides that encode SEQ ID NO: 2. Furthermore, complements (including fragments and portions of SEQ ID NO: 1) placed inside a vector and consequently a host cell would not encode a protein or the protein of SEQ ID NO: 2.. There is no guidance as to how to use these divergent sequences. The encoded products of these 90% sequence identical nucleic acids may possess function that is not commensurate with the functions of the native protein. The nucleic acids will encode proteins that may not maintain the activities proposed in the specification, such as a marker for distinguishing between tumors, which will or have metastasized. Likewise, it would seem that specific function(s) would be required to make the encoded protein useful for the applications disclosed in the specification. Since the amino acid sequence of a polypeptide determines its structural and functional properties, predictability of which changes can be tolerated in a polypeptide's amino acid sequence and still retain similar activity requires a knowledge of and guidance with regard to which amino acid or acids in the polypeptide's sequence, if any, are tolerant of modification and which are conserved and detailed knowledge of the ways in which the

protein's structure relates to its function. The specification provides essentially no guidance as to which of the infinite possible choices is likely to be successful especially in selection of at least one conservative amino acid substitution within the range *of about 1 to about 273 amino acid residues of SEQ ID NO: 2* (see claim 5). The true fact of the state of the art in peptide chemistry is expressed succinctly in the accompanying Lazar article (Molecular and Cellular Biology 8(3): 1247-1252, March 1988). This article presents data that substantiates the fact that the introduction of mutations in an amino acid sequence will yield products with different biological activity from the wild type protein.

From the discussion above, it is clear that the predictability of changes to the nucleic acid sequence and its forthcoming amino acid sequence is practically nil as far as biological activities are concerned. Moreover, a complement sequence(s) more than likely would not encode a protein or result in expression of polypeptide consistent with SEQ ID NO: 2. The specification fails to provide sufficient guidance to enable one of ordinary skill in the art to make and use the claimed nucleic acids in a manner reasonably correlated with the broad scope of the claims. Without such guidance, the changes which must be made in the nucleic acid sequence of SEQ ID NO: 1, which results in nucleic acid sequences with 90% identity is unpredictable and the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue. See *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016 and *Ex parte Forman*, 230 USPQ 546 (BPAI 1986).

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-11 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication number 2002/0081659 A1 (published June 27, 2002, filing date March 12, 1999). Applicants' claim language in section d of claim 1 reads "the polynucleotide complement of the polynucleotide of (a), (b), or (c)". In particularity the term "complement" embraces a genus of polynucleotides of any size and any amount of sequence complementarity necessitating the instant rejection. U.S. Patent Application Publication #2002/0081659 discloses sequence 171 which is an isolated nucleic acid molecule comprising a polynucleotide complement of the polynucleotide of sections (a), (b) and (c) of claim 1, see the attached database sheets. Furthermore, the disclosed nucleic acid sequences are a polynucleotide at least 90% identical to the polynucleotide complement described in sections (a), (b) and (c) of claim 1. Polynucleotide residues 94-584 of sequence 71 are the same as Applicants' nucleic acid residues 700-1191; nucleic acid residues 586-1212 of sequence 71 are the same as Applicants' nucleic acid residues 1193-1818; and nucleic acid residues 1216-1369 of sequence 71 are the same as Applicants' nucleic acid residues 1822-1976 of SEQ ID

NO: 1. There are at least 89-623 contiguous nucleotides from the coding region of Applicants' SEQ ID NO: 1, see attached database sheets. The disclosed isolated nucleic acid molecules comprise a polynucleotides encoding a polypeptide with at least one conservative amino acid substitution having an amino acid sequence within a range of amino acids 1 to about 273 of SEQ ID NO: 2.

The disclosed isolated nucleic acid molecules are able to be packaged in a recombinant vector and further into a recombinant host cell for the production of polypeptides, see pages 79 and 80, sections 0124-0133.

7. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Boehringer Mannheim Biochemicals 1991 Catalog, page 557. Applicants' claim language in section d of claim 1 reads "the polynucleotide complement of the polynucleotide of (a), (b), or (c)". In particularity the term "complement" embraces a genus of polynucleotides of any size and any amount of sequence complementarity necessitating the instant rejection. Accordingly, the following rejection is set forth. Boehringer's catalog discloses a chemically synthesized mixture of hexanucleotides containing all possible 6-nucleotide sequences, which has a polynucleotide complement of the polynucleotide of sections (a), (b) or (c) of claim 1.

Double Patenting

8. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to

identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

9. Claims 1-11 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-11 of copending Application No. 10/200,026 (filed July 18, 2002). This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571) 272-0831. The examiner works a flexible schedule, but can normally be reached between the hours of 6:30 am to 5:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER

Alana M. Harris, Ph.D.
08 October 2004